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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,191	03/10/2005	Leif Kongerslev	KONGERSLEV2	1109

1444 7590 06/01/2007

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EXAMINER	
MONDESI, ROBERT B	
ART UNIT	**PAPER NUMBER**
1652	

MAIL DATE	DELIVERY MODE
06/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,191	KONGERSLEV ET AL.	
	Examiner	Art Unit	
	Robert B. Mondesi	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,9,11,13,15,17,18,20-33,37,39-42,49 and 52-64* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 15, 26, 58, 62 and 64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 March 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 5-7,9,11,13,17,18,20-25,27-29,31-33,37,39-42,49,52-57,59-61 and 63.

DETAILED ACTION

Response to restriction requirement

Applicants' election with traverse of Invention of Group I, **Claims 1, 3-7, 9, 11, 13, 15, 17-18 and 20-30** and the further election of residues 1-77 of SEQ ID NO: 125 (first polypeptide) and residues 80-228 of SEQ ID NO: 126 (second polypeptide) in amendment, filed February 20, 2007 is acknowledged. The traversal is on the ground(s) that the fusion proteins according to claim 1 indeed are novel over the cited publications; applicants also assert that they do not understand why the election of a patentably distinct product with regards to SEQ ID NO: is not a species election. Applicants have asserted further that they have provided numerous alignments comparing all the second polypeptides (designated by at least 20 SEQ ID NO:s) that should also be examined.

This is not found persuasive because the independent **claim 1** is drawn to a first polypeptide comprising a polypeptide which is 70% identical to a lectin complement activating pathway protein or any fragment, comprising at least thirty consecutive amino acids and a second polypeptide comprising any fragment of at least thirty amino acids that is capable of associating with one or more carbohydrates. With all due respect to the applicants assertions, the scope of this claim includes hundreds of peptides that have no underlying technical feature besides the applicants statement that they associate with carbohydrates. There is no unity invention among these hundreds of fragments and contrary to applicants' allegations these proteins are well known in the

art and are disclosed in a multitude of publications, see for example rejections under 35 U.S.C 103(a) below.

Examination of Patent Applications Containing Nucleotide Sequences

I. Summary

The United States Patent and Trademark Office (Office) published an Official Gazette notice in November of 1996 providing a partial waiver of the requirements for restriction pursuant to 37 CFR 1.141 et seq. and for unity of invention determinations pursuant to 37 CFR 1.475 et seq. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 Off. Gaz. Pat. Office 68 (Nov. 19, 1996) (1996 Notice). The 1996 Notice permitted examination of a reasonable number, normally up to ten, independent and distinct molecules described by their nucleotide sequence in a single patent application. The Office has reconsidered the policy set forth in the 1996 Notice in view of changes in the complexity of applications filed, the types of inventions claimed and the state of the prior art in this technology since that time. Because of these changes, the search and examination of up to ten molecules described by their nucleotide sequence often consumes a disproportionate amount of Office resources over that expended in 1996. Consequently, with this Notice the Office rescinds the partial waiver of 37 CFR

1.141 et seq. for restriction practice in national applications filed under 35 U.S.C. 111(a), and 37 CFR 1.475 et seq. for unity of invention determinations in both PCT international applications and the resulting national stage applications under 35 U.S.C. 371. This Notice is effective immediately and is applicable to all pending applications.

Note, however, that supplemental restriction requirements will not be advanced in applications that have already received an action on their merits in the absence of extenuating circumstances.

II. Background

In 1996, the Office held public hearings to address concerns relating to patent protection of nucleic acids described by their nucleotide sequences. The ease of using automated techniques for sequencing large numbers of nucleotides resulted in the filing of a growing number of patent applications, many of which recited thousands of individual nucleotide sequences. After the public hearings, the Office modified its restriction and unity of invention practice for the examination of patent applications that claim large numbers of polynucleotide molecules described by their nucleotide sequences in an effort to encourage and promote growth in this technology while taking into account the unprecedented search and examination challenges that such applications pose.

In the 1996 Notice, the Office partially waived the requirements of 37 CFR 1.141(a) and permitted applicant to claim and have examined in a single application a reasonable number, normally up to ten, independent and distinct inventions described by their nucleotide sequences. At that time, the Office determined that such a practice would not create an undue burden on the Office and would promote efficient, cost effective examination of these types of applications. The Office made a similar revision to practice for search and examination of applications filed under the PCT. Pursuant to the partial waiver of 37 CFR 1.475 et seq., up to ten nucleotide sequences would be

searched and/or examined in international applications or national stage applications filed under 35 U.S.C. 371; where applicants paid a fee for search and/or examination of at least one additional group (see 37 CFR 1.476(b)), up to four additional sequences would be searched and/or examined per group.

Patent applications that prompted the public hearings and the 1996 Notice often disclosed multiple partially characterized complementary DNA (cDNA) molecules, discovered by expressed sequence tag (EST) techniques, that were claimed and described by simple reference to a nucleotide sequence. At that time, and in many of those applications, little information was provided relating to function of the nucleic acid, nor was there significant description of the function or the information content (e.g., protein coding capacity) of the nucleic acid claimed. Consequently such claims were, in many instances, simple in format and narrow in scope. Often, the examination of narrowly drawn claims to EST-type nucleic acid molecules required little more than automated database searches. Further, the review and analysis of sequence search results could be accomplished within examination time constraints.

Since 1996, the technology has evolved and the types of nucleic acid sequence-based claims have become more diverse and complex. In 1996, polynucleotide molecules were often claimed by simple reference to a nucleotide sequence. Polynucleotide molecules are now often claimed in a single application in a variety of complex formats, some of which may embrace multiple inventions, such as by reference to: the amino acid sequence of the protein encoded; the ATCC number of a deposited plasmid containing the polynucleotide molecule; arbitrary laboratory designations;

function of the nucleic acid alone or in combination with a partial linear nucleotide sequence; a genus described in terms of homology, percent identity, or hybridization; a genus (or subgenus) described by nucleic acid sequence with variable positions specified within the sequence listing; single nucleotide polymorphisms (SNPs); antisense; or interfering RNA. .

Advances over the past ten years in automated sequencing and polynucleotide characterization techniques have made such activities routine. The entire genome of several organisms, including humans, has been determined and deposited into nucleotide sequence databases. Consequently, patent applications claiming large numbers of lengthy polynucleotides, such as full-length open reading frames and entire genomes, have become more the norm rather than the exception. The advances in nucleic acid sequencing techniques have also lead to the exponential growth in the size of nucleic acid sequence databases and an increase in the number and complexity of such databases.

The GenBank® database in 1996 contained 651,972,984 nucleotides in 1,021,211 sequences. In 2000 the database contained 11,101,066,288 nucleotides in 10,106,023 sequences, about a seventeen-fold increase in the number of nucleotides and about a tenfold increase in the number of sequences. In February 2006, the GenBank database contained 59,750,386,305 bases in 54,584,635 sequence records or about a ninty-one-fold increase in the number of nucleotides and about a fifty-four-fold increase in the number of sequences.

These factors are responsible for exacerbating the search and examination burden faced by the Office with respect to polynucleotide inventions claimed and described in currently filed applications. It now requires significantly more computational time to run individual nucleotide sequence searches for examination purposes than in 1996, and there is significantly more pertinent prior art to consider. In addition, it currently takes more Office resources to correlate the claimed polynucleotide with the polynucleotide as defined in the prior art because it is increasingly common for both patent applicants and prior art references to describe a polynucleotide molecule in different ways.

The foregoing illustrate that the evolution of the technology and current claim drafting practices are placing an ever-growing resource burden on the Office to search and examine patent applications disclosing and claiming nucleotide sequences. Rescission of the1996 Notice is intended to enhance the Office's ability to provide a focused, thorough and quality examination of polynucleotide inventions, and to lead to consistency in the examination of polynucleotide molecules, regardless of the manner in which they are claimed, and equitable use of Office computational and examination resources.

III. Examination Guidelines

For National applications filed under 35 U.S.C. 111(a), polynucleotide inventions will be considered for restriction, rejoinder and examination practice in accordance with the standards set forth in MPEP Chapter 800 (except for MPEP 803.04 which is superceded by this Notice). Claims to polynucleotide molecules will be considered for

independence, relatedness, distinction and burden as for claims to any other type of molecule.

For International applications and national stage filings of international applications under 35 U.S.C. 371, unity of invention determination will be made in view of PCT Rule 13.2, 37 CFR 1.475 and Chapter 10 of the ISPE Guidelines. Unity of invention will exist when the polynucleotide molecules, as claimed, share a general inventive concept, i.e., share a technical feature which makes a contribution over the prior art.

Therefore the requirement is still deemed proper and is made FINAL.

Claims 2, 8, 10, 12, 14, 16, 19, 34-36, 38, 43-48 and 50-51 have been canceled. **Claims 52-64** have been added. **Claims 1, 3-7, 9, 11, 13, 15, 17-18, 20-33, 37, 39-42, 49, 52-64** are pending in this application. **Claims 5-7, 9, 11, 13, 17-18, 20-25, 27-29, 31-33, 37, 39-42, 49, 52-57, 59-61 and 63** are withdrawn from further consideration because these Claims are drawn to non-elected inventions. **Claims 1, 3, 15, 26, 58, 62 and 64** are currently under examination.

Priority

The current application filed on march 10, 2005 is a 371 of PCT/DK03/00585 filed on 09/10/2003, which in turn claims priority to foreign application, DENMARK PA 200201328 filed on 09/10/2002. A certified copy of foreign document 200201328 has been provided.

Preliminary Amendment

The preliminary amendment filed October 13, 2005 has been entered.

Drawings

Drawings filed March 10, 2005 have been objected to because Figures 1-3 contain text that appear to be description of the drawing and not related to an office acceptable legend under 37 CFR 1.84(o), such description belongs in the Brief Description of the Drawings in the specification of the application (The mentioned text appears below each Fig.). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Information Disclosure Statement

The IDS filed October 13, 2005 has been received and is signed and considered, a copy of the PTO 1449 is attached to the following document.

Specification

Examiner would like to point out that there is no information with regards to SEQ ID NO: of the nucleic acid sequences present in Figures 1-3, 9 and 10 in the Brief Description of the Drawings for the mentioned Figures 1-3, 9 and 10. If the Drawings contain amino acid sequences that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a((1) and (a)(2) then the Brief Description of the Drawings needs to state the SEQ ID NO: for the nucleotide and/or amino acid sequences. Unless the appropriate SEQ ID NO: accompanies the nucleotide and/or amino acid sequences in the actual Drawing sheet.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a fusion protein comprising a first protein comprising the residues 1-77 of SEQ ID NO: 125 and a second polypeptide comprising residues 88-228 of SEQ ID NO: 126, does not reasonably provide enablement for a fusion protein comprising i) a first polypeptide sequence derived from a lectin-complement pathway activating protein or a functional homologue at least 70% identical

to said lectin-complement pathway activating protein, wherein said first polypeptide sequence is capable of activating protein, wherein said first polypeptide sequence is capable of activating the lectin-complement pathway; and ii) a second polypeptide sequence derived from a collectin or a functional homologue at least 70% identical to said collectin, wherein said second polypeptide sequence is capable of associating with one or more carbohydrates; wherein said complement activating protein is not a collectin, wherein said first polypeptide sequence is capable of associating with at least one MASP protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir.1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the predictability

or unpredictability of the art, (5) the relative skill of those in the art, (6) the amount or direction or guidance presented, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary. Although the quantity of experimentation alone is not dispositive in a determination of whether the required experimentation is undue, this factor does play a central role. For example, a very limited quantity of experimentation may be undue in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not be undue when viewed in light of some guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome classification as undue experimentation. In Wands, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation would result in successfully obtaining the claimed invention. (Wands, 8 USPQ2d 1406). Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination of Wands factors, which provide a very low likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

1-2 .Breadth of the claims and the nature of the invention..

In regards to the product of the invention and the breadth of the claims the broadest interpretation that applies is a fusion protein comprising i) a first polypeptide sequence derived from a lectin-complement pathway activating protein or a functional homologue at least 70% identical to said lectin-complement pathway activating protein, wherein said first polypeptide sequence is capable of activating protein, wherein said first polypeptide sequence is capable of activating the lectin-complement pathway; and ii) a second polypeptide sequence derived from a collectin or a functional homologue at least 70% identical to said collectin, wherein said second polypeptide sequence is capable of associating with one or more carbohydrates; wherein said complement activating protein is not a collectin, wherein said first polypeptide sequence is capable of associating with at least one MASP protein.

3-4. The state of prior art and the level of predictability in the art.

Endo et al., 1996 teach that collectins are a subfamily of C-type lectins such as a mannan binding protein. Endo et al. disclose a novel human lectin, P53, which has collagen type domain and specifically recognizes G1cNAc residues and unlike collectin with a well conserved carbohydrate-recognition domain (CRD), P53 possess a fibrinogen-like domain (FBG) at the COOH-terminal region. The overall structure of P35 resembles those of two pig ficolins that are putative receptors on unterine cells membranes; however the homology percentages did not reveal a clear relationship among the proteins. Endo et al., teach further that although the function common to FBG's remain unknown, at least one type of FBG appears to play an important role in cell-cell interactions via ligand molecules on target cells. These findings suggest that

P53 and other members of its family may be bi- or multifunctional proteins. Furthermore three type of splicing variants were isolated and at present time, no information regarding their translation in liver or the secretion of their products into the circulation is currently available. Endo et al. conclude that more studies are needed to elucidate the function of each member of the P53 family and to establish the structural and functional relationships among them. It is important to note that Endo et al. disclose an amino acid sequence that is 100% identical to residues 1-77 of SEQ ID NO: 125, see figure 3, on page 518.

5. The relative skill in the art.

The relative skill in the art as it relates to the product of the invention is characterized by that of a M.D. or Ph. D. level individual.

6-7. The amount of guidance present and the existence of working examples.

Applicants have provided an extremely small amount of guidance with regards to a fusion protein comprising i) a first polypeptide sequence derived from a lectin-complement pathway activating protein or a functional homologue at least 70% identical to said lectin-complement pathway activating protein, wherein said first polypeptide sequence is capable of activating protein, wherein said first polypeptide sequence is capable of activating the lectin-complement pathway; and ii) a second polypeptide sequence derived from a collectin or a functional homologue at least 70% identical to said collectin, wherein said second polypeptide sequence is capable of associating with one or more carbohydrates; wherein said complement activating protein is not a collectin, wherein said first polypeptide sequence is capable of associating with at least

one MASP protein. On pages 100-108 of the instant applicants applicants have provided fusion constructs expressed in cells lines but very little information has been provided in regards to these limited constructs. On page 110 of the instant application the activities of a small number of constructs have been disclosed.

8. The quantity of experimentation necessary.

The amount of experimentation that is required is undue: while to make and use a fusion protein comprising a first protein comprising the residues 1-77 of SEQ ID NO: 125 and a second polypeptide comprising residues 88-228 of SEQ ID NO: 126 could be considered routine, to make and use a fusion protein comprising i) a first polypeptide sequence derived from a lectin-complement pathway activating protein or a functional homologue at least 70% identical to said lectin-complement pathway activating protein, wherein said first polypeptide sequence is capable of activating protein, wherein said first polypeptide sequence is capable of activating the lectin-complement pathway; and ii) a second polypeptide sequence derived from a collectin or a functional homologue at least 70% identical to said collectin, wherein said second polypeptide sequence is capable of associating with one or more carbohydrates; wherein said complement activating protein is not a collectin, wherein said first polypeptide sequence is capable of associating with at least one MASP protein is not routine and requires more experimentation. Therefore, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, and the high degree of unpredictability as evidenced by the prior art, undue experimentation would be

necessary for a skilled artisan to make and use the entire scope of the claimed invention.

It must be noted that the issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. The Applicants make and test position is inconsistent with the decisions of *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "... scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands*, 858 F.2d at 737, 8 USPQZd at 1404 (Fed. Cir. 1988). Therefore, for the instant specification to be enabling, it needs to provide direction/guidance regarding an acceptable number of different fusion protein constructs.

Absent sufficient guidance/direction one of skill in the art would not be able to practice the claimed invention commensurate in scope with the claims. Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and insufficient working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art, attempting to test all the different type fusion

proteins encompassed by the claimed invention would constitute undue experimentation. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 15, 26, 58, 62 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thiel et al., WO 02/06460 (cited in the IDS filed March 10, 2005) and Endo et al., 1996 in light of Matsushita et al., 2002 (cited in the IDS filed March 10, 2005).

Thiel et al. disclose an amino acid sequence that is 100% identical to the amino acid sequence comprising residues 80-228 of SEQ ID NO: 126 (see sequence alignment analysis provided by STIC attached to the instant Office action and cited in PTO-892). Thiel et al. teach that the polypeptide of the invention can be fused to another protein to form a fusion partner (page 27, lines 25-32).

Thiel et al. do not teach specifically that the fusion partner of the polypeptide of their invention comprises residues 1-77 of SEQ ID NO: 125.

Endo et al., 1996 teach that collectins are a subfamily of C-type lectins such as a mannan binding protein. Endo et al. disclose a novel human lectin, P53, which has collagen type domain and specifically recognizes G1cNAc residues and unlike collectin with a well-conserved carbohydrate-recognition domain (CRD), P53 possess a fibrinogen-like domain (FBG) at the COOH-terminal region. The overall structure of P35 resembles those of two pig ficolins that are putative receptors on unterine cells membranes (page 515, column 1, line 1 through column 2, line 15). Endo et al. disclose an amino acid sequence that is 100% identical to residues 1-77 of SEQ ID NO: 125, see figure 3, on page 518.

Matsushita et al. teach that MBL (amino acid sequence disclosed in Thiel et al.) and filicon/P53 (amino acid sequence disclosed by Endo et al.) have structural and functional similarities as they both are active in the animal lectin pathway that prevents infection through the innate immune system in which they aggregate microorganisms and in some cases act as opsonin (page 2281, column 1, lines 1-4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine an MBL polypeptide comprising residues 80-228 of SEQ ID NO: 126 with a filicon/P53 polypeptide comprising residues 1-77 of SEQ ID NO: 125 for the advantages of a fusion polypeptide that can act as an opsonin as taught by Thiel et al., Endo et al. and Matsushita et al., see Matsushita et al at column 1, lines 1-4. Furthermore, applicants are reminded that, " It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.)

Also it is important to note that The US Federal Circuit has recently explicitly stated that in order to make a *prima facie* case of obviousness, the suggestion and motivation to combine said references need not be explicitly stated in the text of the references. Rather, consideration of common knowledge and common sense when combining references is not only permitted *but required*. See DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 80 USPQ2d 1641 (Fed. Cir. 2006) which states:

> ""Suggestion" test for obviousness does not require that suggestion, teaching, or motivation to combine cited prior art references be found in references themselves, or that such suggestion or motivation be explicitly stated; suggestion test is flexible rather than rigid and categorical, recognizing motivation to combine found in knowledge of persons of ordinary skill in art or nature of

problem to be solved, as well as in references, and test not only permits, but requires, consideration of common knowledge and common sense."

It would be completely reasonable that a person with ordinary skill in the art would have the common sense and the common knowledge to combine the above references in order to produce the claimed fusion polypeptide of the instant application.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert B Mondesi
Examiner
Art Unit 1652

Robert B. Mond
5-25-07